

# Profile of the pharmaceutical industry and relevant sector aspects

## Pharmaceutical market in Brazil

Based on information from the pharmaceutical market auditorium, IQVIA, in 2017 the Brazilian drug market handled R\$ 56.80 billion or USD 17.79 billion (Pharmacy channel, net value - average discount of 40.55%), with a growth, in reais, 11.73% over the same period of the previous year, which represents approximately 2% of the world market, being the 8th in the ranking of the twenty major economies. In Latin America, it is the main market, ahead of Mexico (USD 5.4 billion) and Argentina (USD 5.4 billion).



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### Industry profile

In 2017, the national drug market was composed of 241 pharmaceutical laboratories, which were regularized and priced at CMED, thus being authorized to market drugs. Of the 241 laboratories, 97 (40%) own the capital of international origin and 144 (60%) own the capital of national origin.

Within the pharmacy channel, multinational companies hold approximately 52.44% of the market in sales and 34.75% in units sold (boxes); The national laboratories present about 47.56% of the market in sales and 65.25% in units sold (boxes). The growing share of generic medicines has given domestic companies the leadership in unit sales.

### Trade balance

According to the Ministry of Industry, Foreign Trade and Services, in 2017 the pharmaceutical industry's exportations were USD 1.247 billion, an increase of 3.82% over the same period of the previous year. This amount represents a growth of just over five times in relation to the year 2000. Importations of finished products, semi-finished products, vaccines, blood products and other pharmaceuticals reached USD 6.557 billion - an increase of 2.63% in comparison with the same period of 2016.

### Jobs

For the Ministry of Labor and Employment, the Brazilian pharmaceutical industry closed the year 2016 with 97,228 thousand direct jobs, 1,759 employees in pharmaceutical manufacturing companies, 9,375 in companies manufacturing veterinary drugs, and 86,094 in pharmaceutical companies manufacturing medicinal products for human use. Among the pharmaceutical companies destined to manufacture medicines for human use, 55.4% are based in the State of São Paulo. For the year 2016, industrial employment in São Paulo registered a slight positive variation of 0.09%.

### Development of the sector

The development of the pharmaceutical sector should be based on the following tripod: stimulating local production, stimulating innovation, adopting public policies for access to medicines.

### Industrial policy

The pillar of a successful industrial policy for the pharmaceutical sector is long-term financing with subsidized interest rates. A small advance occurred with the creation of the Profarma Programs by BNDES, whose financial contributions are insufficient to meet the demand of the sector in relation to research and development. Other aspects should be in a policy of technological innovation, with a stable and defined regulatory framework, which contemplates the development of the sector.



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### Economic regulation

An economic regulation system in tune with the fundamentals of the economy does not support price control mechanisms such as the ones that the country has been using in the last decades. Economic regulation should serve as an instrument to improve the market, stimulate the research of innovative products and establish an environment conducive to investment in general, protecting the consumer by ensuring a healthy market. There is a need to modernize current price regulations.

### Price control

Adopted unilaterally and without a broad, articulated and long-term economic strategy, price controls have in the past disrupted the pharmaceutical chain and inhibited investments in factories and the launching of medicines. This control should be selective and not comprehensive, as it currently is, being restricted to the drug classes for which the market can be considered imperfect (low competition).

### Readjustments

Since the end of 2000, the pharmaceutical industry has been subject to strict price controls. Between March 2000 and February 2017 - the month prior to the granting of the last annual readjustment by the CMED, with a weighted average readjustment for the year 2017 of 2.63%, Extended Consumer Prices (IPCA), by IBGE, totaled 200%. Recalling that the IPCA is currently one of the factors that make up the annual price readjustment formula authorized by the CMED. In the same period, the index of replacement of costs of the pharmaceutical sector, authorized by the regulatory authorities, was of 162,99%.

### Tax burden

The high tax burden on human medicines, which represents an average of 31.3% of the consumer price - one of the highest in the world, prevents products from reaching the final consumer at an even lower price. In Portugal, for example, the tax on medicines is 6%. Mexico does not charge taxes. Compared to other sectors, the products whose destination is agriculture or livestock, receive tax benefits of ICMS, Pis, and Cofins. Thus, compared to the 31.3% of the tax burden of medicinal products for human use, animal medicines have a 13.11% tax burden. An important movement occurred in the State of Paraná, which reduced the ICMS rate to 12%. This same movement occurred in Minas Gerais and São Paulo, for generic drugs. However, as of 2017, some states have increased their tax burden by up to 1%. Sindusfarma did not abandon its mission of fighting for the adoption of a tax burden equivalent to zero on medicines in Brazil.



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### Fiscal War

The dispute between states for the attraction of companies of sectors of economic relevance, through the concession of fiscal incentives, has affected especially the pharmaceutical pole of São Paulo - the main one of the country -, causing losses to the productive chain in establishing a possible competition disloyalty by the use of the so-called "tax invoice ride".

### Access to medicines

Despite price controls, the access situation has changed little in the last decade, which shows that the main obstacle to expanding access to medicines is not price: they are, in fact, insufficient pharmaceutical within the Unified Health System and the low average purchasing power of the Brazilian population. It is a fact that public funds for universal purchase and distribution of medicines have increased in recent years, but the country still invests little in health: 8% of GDP, much less than developed countries.

### Public expenditure on medicines

Regarding the amounts allocated to the actions of the Ministry of Health related to the acquisition/production/research of medicines, 2017 presented a different behavior from previous years. While 2016 showed strong values of R\$ 15.5 billion and 21% growth over 2015, the year 2017 showed a deceleration of 8% in expenses, staying in the house of R\$ 14.3 billion reais.

### Popular Pharmacy Program of Brazil

The program that began in 2004 operates today on two fronts: gratuity and co-payment. Providing free medications for hypertension, diabetes, and asthma, the program also offers medicines with the cost of up to 90% cheaper to treat dyslipidemia, rhinitis, Parkinson's disease, osteoporosis, and glaucoma, as well as contraceptives and geriatric diapers for urinary incontinence. This type of initiative, by public managers, should be extended, since it provides an effective and consistent extension of the population's access to medicines. The creation of the Popular Pharmacy Program in Brazil represented a breakthrough in the health system, in keeping with an old thesis of the pharmaceutical industry, according to which the development of the pharmaceutical chain should contemplate the social function of expanding the consumer drug market (of which millions of Brazilians are excluded), without, however, disregarding the economic logic. The future of the pharmaceutical industry in the country depends on initiatives like this, which point to the desi-



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red situation of convergence of projects and synergy between government and private initiative. In 2017, the government spent 2.88 billion reais on the acquisition of medicines for the program, dispensing 13.33 billion pharmacotechnical units (tablet, ampoule, dose, etc.). These figures represent growth of 4.8% and 8.6%, respectively. Unfortunately, because of the huge problems in which public finances lie, the federal government threatens to reduce the program, at least part of it, in the coming months.

### Health care providers in Brazil

Currently, in Brazil, there are 1,056 healthcare providers, with active registration and registered beneficiaries, which had revenues of R\$ 144.34 billion up to the third quarter of 2017, according to data reported to the National Health Agency (ANS). According to the regulatory agency, in December 2017 the number of health plan beneficiaries reached 70.5 million, with 47.3 million beneficiaries in health care plans and 23.2 million beneficiaries in exclusively dental plans.

### State laboratories

The production of medicines by state laboratories must meet the strategic objectives of the public health policy of the country, such as the manufacture of essential products for which there is no sustainable market. It is not the role of the state to compete with private laboratories in the production of medicines that the private sector is able to produce with better quality and at lower prices for the consumer. These laboratories have in recent years had government incentives to absorb technologies through the Productive Development Partnership (PDPs).

### Generic medicine

In recent years, the segment has been gaining more and more space in the market. In 2017, generics were responsible for 13.2% of sales, sales of medicines from pharmacies, and 32.5% of units sold.

### Innovation

The Innovation Law is a fundamental action for the strengthening of the pharmaceutical industry. The country lacks guidelines that link the relationship between private initiative and public institutions, such as the universities' research centers. There is a need for greater subsidized public funding in this segment since the risk with the research is great and the result uncertain. Based



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on policies of growth to national production, the government through the GECIS (Executive Group of the Industrial Complex of Health) the condition for effective action of local companies in the art of Research and Development. PDP policy is also an important lever for innovation.

### Research

Brazil has favorable conditions to become an advanced research center. Its biodiversity – the largest in the world – increases the country's potential for investment. To better take advantage of these resources, a policy that emphasizes Innovation, encouraging investments, a more intense exchange between Brazilian and international researchers and, especially, a defined, stable regulatory framework that adequately protects intellectual property is needed. The actions of the Ministry of Health to expedite the approvals of the Clinical Studies in Brazil have improved the local environment for this investment. Both CONEP (National Commission for Research Ethics) and Anvisa have reduced approval periods for local clinical studies, but there is a need to modernize regulatory frameworks and better define the rights of research subjects.

### Patents

The same country that defines as a priority of its industrial policy support for research, development of drugs and medicines and the exploitation of biodiversity adopts hazy criteria to reject internationally recognized patents. The INPI (National Institute of Industrial Property) is scrapped and without technical conditions to analyze the patent applications in reasonable time frames.

### Foreign trade stimulus

The expansion of the pharmaceutical sector in Brazil through the conquest of foreign markets depends on a tariff modernization, which includes, among other measures, the revision of import taxes and the removal of barriers to exports. Some Brazilian companies are in the process of internationalization.

### Health regulation

Health regulation should be an instrument to guarantee the quality and safety of medicines, and consumer protection, without creating unnecessary limitations on the industry. To achieve this goal, regulatory agencies need to equip themselves with sufficient staff and infrastructure to perform their role comprehensively and effectively. Today Anvisa is recognized as one of the best health agencies in the world. It still has problems with deadlines.



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### Safety and traceability

The creation of the National Drug Control System, through Law 11,903/2009, amended by Law 13,410, of December 28, 2016, contemplated the permanent position of the pharmaceutical industry in favor of improving the traceability mechanisms of medicines sold in the country. In 2017, RDC No. 157/2017 was published, which provides for the implementation of the National Drug Control System and the mechanisms and procedures for drug tracing, which is in the experimental phase.

### Sindusfarma, in order to concretize the above topics, actively participates in the following groups:

- **CONITEC (National Commission for the Incorporation of Technologies in SUS)** – The incorporation of new technologies into the Unified Health System is important for the development of access and industry in Brazil.
- **CNS (National Health Council)** – This council determines the health policies of the country and Sindusfarma defends the valorization of the pharmaceutical industry established in Brazil.
- **Anvisa Advisory Council** – The participation of Sindusfarma, representing the Health Industry in Brazil, aims to defend the needs of the regulated sector with transparent, feasible and predictable legislation.
- **COPIN (Council of Industrial Policy and Technological Development of CNI)** – In the National Confederation of Industry, Sindusfarma defends public and private policies for the development of the Pharmaceutical Industry installed in Brazil, regardless of the origin of the company's capital.
- **GECIS (Executive Group of the Industrial Health Complex)** – Defines policies to increase production and innovation of health products in Brazil. Sindusfarma's mission is to defend the non-discrimination of capital in the incentive policies.
- **COMPETE SP (Paulista Council of Competitiveness)** – Organism of incentive to the production in the State of São Paulo. Sindusfarma participates in creating a favorable environment for the Pharmaceutical Industry in the State of São Paulo.



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- **COMSAÚDE FIESP** – COMSAÚDE was created to support the entities of the productive chain of health, biotechnology, and nanotechnology. COMSAÚDE seeks to establish an impartial communication with the entire health sector, encouraging dialogue between the parties and fostering dialogue among all parties involved.

In order to leverage the above themes, in addition to Sindusfarma's participation in the aforementioned bodies, we held several seminars, working groups, strategic commissions, workshops, bringing universities, government and industry closer together, aiming at transmitting knowledge and enabling transversal dialogue.

### Sources:

- Market of Regulation of the Market of Medicines (CMED);
- European Commission;
- National Council of Finance Policy (CONFAZ);
- Brazilian Institute of Geography and Statistics (IBGE);
- IQVIA;
- Ministry of Industry, Foreign Trade, and Services (MDIC);
- Ministry of Health (MS);
- Ministry of Labor and Employment (MTE);
- Integrated Government Planning and Budgeting System (SIOP);
- World Health Organization (WHO).